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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,885	11/20/2001	Susana Salceda	DEX-0279	3414

7590 10/14/2004

Licata & Tyrrell P.C.  
66 East Main Street  
Marlton, NJ 08053

EXAMINER

MARTINELL, JAMES

ART UNIT PAPER NUMBER

1631

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/001,885

Applicant(s)

SALCEDA ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-13, 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/20/03 & 7/30/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Applicant's election with traverse of the requirement for restriction in the reply filed on June 28, 2004 is acknowledged. The traversal is on the ground(s) that no undue burden of search would be required to search both nucleotides and polypeptides and that at least 10 sequences should be searched. This is not found persuasive because the searches of the nucleotides and polypeptides are not co-extensive. In connection with the search of 10 sequences and the citation of MPEP 803.04, it is noted that the OG notice of November 19, 1996 did not create a right for the search of 10 inventions in a single application. It is further noted that the OG notice states that up to 10 unrelated sequences may be searched in a single application. One sequence searched in a single application is within the range of up to 10 sequences searched in a single application.

The requirement is still deemed proper and is therefore made FINAL.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Embedded hyperlinks and/or other form of browser-executable codes occur in at least the following locations:

- (a) page 55, lines 21-31,
- (b) page 61, lines 1-2, and
- (c) page 62, lines 4-5.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9, 14, and 15 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for either the nucleotide sequence SEQ ID NO: 31 or the polypeptide of amino acid sequence SEQ ID NO: 125. There is no disclosure of any nexus between either one of the SEQ ID NOs and any condition or disease.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The discussion in the previous rejection is incorporated here. In addition, the claims are broader than the enabling disclosure in that the instant application does not teach how to make and use the full scope of polynucleotides embraced by the claims. The instant application does not teach a use for all of the polynucleotides that are at least 60% identical to SEQ ID NO: 31 (*e.g.*, see claim 1(d)). Additionally, the instant application does not teach how to use each of the sequences embraced by claim 1(c). There are no fewer than  $2.4 \times 10^{65}$  nucleotide sequences that encode SEQ ID NO: 125. The instant application does not teach how to make and use the full scope of nucleotides that hybridize specifically to polynucleotides that encode SEQ ID NO: 125.

Claims 1-9, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application does not provide an adequate written description of all of the nucleic acids that hybridize specifically to all of the polynucleotides that encode SEQ ID NO: 125. There are no fewer than  $2.4 \times 10^{65}$  nucleotide sequences that encode SEQ ID NO: 125, and so there are considerably more nucleic acids that hybridize specifically to that large number of polynucleotides.

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Claims 1-9, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) Claim 1 is vague and indefinite in that it claims more nucleotides than were elected.
- (b) The recitation of "selectively hybridizes to" (claim 1) is vague, indefinite, and incomplete because selectivity in nucleic acid molecular hybridization depends not only on the probe and the target, but also the presence of other molecules in the reaction mixture that the probe may hybridize to (*e.g.*, see Anderson, "Hybridization Strategy" in *Gene Probe 2: a Practical Approach*, 1995, Hannes et al (eds.), IRL Press, Oxford, pages 1-29, especially section 4, pages 13-16). Thus, the claims are incomplete in that the presence or absence of nucleic acids that may hybridize to the probe is not mentioned.
- (c) The recitation of "selectively hybridizes" (claim 6) is vague, indefinite; and incomplete. The discussion in item (b) hereinabove is incorporated here.
- (d) Claim 14 is vague and indefinite in that it claims non-elected polypeptide assays.
- (e) Claim 15 is vague and indefinite in that it claims non-elected polypeptide kits.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-9, and 15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ruben et al (WO 98/39448 A2 (September 11, 1998)). Ruben et al discloses a nucleic acid that encodes SEQ ID NO: 125 and that has 84.9% sequence identity to SEQ ID NO: 31. Compare Ruben et al Gene 48

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and SEQ ID NO: 58 to SEQ ID NOs: 31 and 125 of the instant application (see the alignments in Appendix A).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

#### **FAX NUMBER**


The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1631**

*10/13/04*